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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/166,701	10/05/1998	ISA ODIDI	SMI-005.01	9432

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EXAMINER	
GEMBEH, SHIRLEY V	

ART UNIT	PAPER NUMBER
1614	

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05/12/2008	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	09/166,701	ODIDI ET AL.	
	Examiner	Art Unit	
	SHIRLEY V. GEMBEH	1614	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *26 February 2008*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1, 4, 7-12, 23, 28-33* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,4,7-12, 23 and 28-33* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

The response filed **2/27/08** presents remarks and arguments to the office action mailed **11/26/07**. Applicant's request for reconsideration of the rejection of claims in the last office action has been considered.

Applicant's arguments have been fully considered but they are not deemed to be persuasive. Rejections and/or objections not reiterated from previous office actions are hereby withdrawn. The following rejections and/or objections are either reiterated or newly applied. They constitute the complete set presently being applied to the instant application.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Status of Claims

Claims 1, 4, 7-12, 23, 28-33 are pending in this office action.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1, 4, 7-12, 23 and 28-33 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the

application was filed, had possession of the claimed invention. This is a new matter rejection.

New matter includes not only the addition of wholly unsupported subject matter, but may also include adding specific percentages or compounds after a broader original disclosure, or even the omission of a step from a method. In other words, the teaching supporting the amendment in instant claim 30 at page 5 with regard to the percentage is less than that claimed in the instant claim 30. For example talc as claimed is 0<10 but in the specification on page 30 the percentage is < than 5 which is narrower than the teachings of the specification. And that applies also to magnesium stearate.

Also the amendment of 15% by weight of hydroxyethyl cellulose and hydroxypropyl cellulose was not disclosed as filed.

Claim Rejections - 35 USC § 102

Applicant's arguments, with respect to the above rejection have been fully considered and are persuasive. The rejection has been withdrawn.

Maintained Claim Rejections - 35 USC § 103

Applicant argues that the Examiner relied upon Weis stating that one of ordinary skill in the art would have been motivated to switch aspirin to naproxen since both are non-steriodal anti-inflammatory drugs. That with regards to Gulley for describing talc and calcium stearate stating that one of skill in the art would have been motivated to substitute calcium and magnesium and that the Examiner relies on Kooichi for

describing a controlled release tablet comprising methacrylic esters. Also that Weiss alone or in combination do not teach the claimed invention.

In response, this is found unpersuasive: Weis teaches controlled release tablet, which is a pharmaceutical delivery. The component of the controlled release tablet are as follows: a blend of polymeric vinyl polymers which is about 1-50%, (see col. 1, lines 35-49 and col. 2, lines 47-60. At col. 5 and 6, the examples comprises of hydroxyl propymethyl cellulose, ethyl cellulose talc and stearic acid.

Guley et al teach a controlled release (tablet) core comprising 20% drug and a mixture of water soluble and water-insoluble polymers at a ratio of 10:1-1.5:1 (column 2 lines 27-36). Hydroxypropyl cellulose and carboxyl vinyl polymer are specified (column 2 lines 42 and 48-49). Sustained release is specified (Title).

Then Kooichi et al. teach a controlled release tablet formation comprising methacrylic and methacrylic esters.

Accordingly all the components required for a controlled release formulation art taught in the prior art. One of ordinary skill in the art would have been motivated to formulate a controlled release pharmaceutical based on the teaching of the prior art to include all the necessary agents because The terms "controlled release" and "delivery" are used in their broadest sense to include mechanisms such as diffusion, chemical and enzymatic reactions, dissolution, osmosis, targeting, as well as the utilization and manipulation of biological processes when this drug is in the system and based on the type of polymer used the drugs protect the drug from releasing during its passage through the body until it reaches its required site. Much of the relevant literature is very

precise in that it either concentrates, for example, on a specific type of polymer offering suitable transport characteristics for an individual permeant, or concentrates on a range of permeants transported through a single polymer type, or concentrates on a unique application. Therefore one of ordinary skill in the art would be motivated to explore which of the polymers known in the art would yield a better controlled release delivery of the drug. See Steward 1995 Review of Pharmaceutical Controlled Release Method and Devices12 pages section under polymers as evident. (Not an introduction of a new literature only to support Examiners view point).

Nothing unobvious is seen in modification and with regards to the concentrations the claims recite about 1%, it is from Examiners point of view that 30 g is more than about 1% for the mixture of hydroxyethyl cellulose and hydroxypropylmethyl cellulose.

Careful consideration has been given but the argument is found unpersuasive and the rejection is maintained and repeated as in the office action of record.

Claims 1, 4, 7-12, 23 and 28-33 rejected under 35 U.S.C. 103(a) as being unpatentable over Weiss et al, US 4,252,786 in view of Guley et al., US 4,309,405 (of record) taken with Kooichi et al. US 4,218,433.

Weiss et al. is applied here as in the above rejection. Claims 23, 30 and 32-33 are taught in part as already discussed in the above rejection. With regard to claims 11 and 29 the reference teaches the active agent to be aspirin a non-steriodal anti-inflammatory drug (NSAID). See col. 5, line 3. One of ordinary skill in the art would

have been motivated to switch aspirin to naproxen another drug of the same category (NSAID) and expect success in doing so.

Guley et al teach a controlled release (tablet) core comprising 20% drug and a mixture of water soluble and water-insoluble polymers at a ratio of 10:1-1.5:1 (column 2 lines 27-36). Hydroxypropyl cellulose and carboxyl vinyl polymer are specified (column 2 lines 42 and 48-49). Sustained release is specified (Title).

Talc and calcium stearate are specified (example 1 column 51). One of ordinary skill in the art would have been motivated to substitute calcium for magnesium and expect a successful result in doing so because both calcium and magnesium are alkaline earth metals and would have expected the same result because of the shared properties. Guley et al. further teach plural water-soluble polymers including hydroxypropyl methyl cellulose and hydroxy propyl cellulose (column 2 lines 40-44).

The combine references do not teach the addition of methacrylic to the said composition, however, Kooichi et al. teach a controlled release tablet formation comprising methacrylic and methacrylic esters. See col. 2, lines 18-30.

One of ordinary skill in the art would have been motivated to combine the above cited references and form a controlled release tablet with a medicament is released either at a sustained or pulsative delivery period of time. The above references make it obvious to one of ordinary skill in the art to make and use the claim invention.

A reference is good not only for what it teaches by direct anticipation but also for what one of ordinary skill in the art might reasonably infer from the teachings. (*In re*

Opprecht 12 USPQ 2d 1235, 1236 (Fed Cir. 1989); *In re Bode* 193 USPQ 12 (CCPA) 1976).

In light of the forgoing discussion, the Examiner concludes that the subject matter defined by the instant claims would have been obvious within the meaning of 35 USC 103(a).

From the teachings of the references, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention. Therefore, the invention as a whole was *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references, especially in the absence of evidence to the contrary.

Double Patenting

Applicant's request that the Double Patenting rejection be held in abeyance until it is made permanent is noted but will be maintained in this Office Action and future Office Actions until withdrawn. Since this is not the only rejection remaining, the double patenting rejection is therefore maintained below.

Claims 1,4,7-12, 23 and 28-33 remain provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims **1 - 22** of U.S. Patent Application No. **11/473,386**. Although the conflicting claims are not identical, they are not patentably distinct from each other.

Claims 1,4,7-12, 23 and 28-33 remain rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims **1 - 28** of U.S. Patent No. **7090867**. Although the conflicting claims are not identical, they are not patentably distinct from each other. The reasons are as follows:

In view of the foregoing, the patented claims and the current application claims are obvious variations.

No claim is allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to SHIRLEY V. GEMBEH whose telephone number is (571)272-8504. The examiner can normally be reached on 8:30 -5:00, Monday- Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ardin Marschel can be reached on 571-272-0718. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

SVG
5/1/08

/Ardin Marschel/
Supervisory Patent Examiner, Art Unit 1614